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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/766,350	12/13/96	CHATTERJEE	M	304142000321

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EXAMINER	
TRAN, M	
ART UNIT	**PAPER NUMBER**
1642	28

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/766,350	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	MAU T TRAN	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2001* .

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,20-24,26-37,39,40,42,43,54-56,59-65 and 67-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,20-24,26-37,39,40,42,43,54-56,59-65 and 67-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *23* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

This Office Action is in Response to Applicant's Amendment filed as Paper #27 on April 12, 2001 in which claim 66 was cancelled, claims 20, 26, 31-32, 35 and 39 were amended and claims 69-73 were added. Claims 1-5, 20-24, 26-37, 39-40, 42-43, 54-56, 59-65, 67-68 and 69-73 are pending.

The Rejections

1. Claim 26 was rejected under 35 USC 112, 2nd for reciting "tandem repeat sequences" as cited in the previous office action paper #25. Applicant's amendment to the claim still cites "random repeat sequences" without further disclosing or clarifying what tandem sequences within SEQ ID NO:33 is being claimed. Further clarification is required.

2. Claims 1-5, 20-27, 31-33, 36-37, 39-40, 42-43, 54-56, 59-65, 67-68 were rejected under 35 USC 102(b) as being anticipated by either Chatterjee (Antigen and Antibody, 1994), Chatterjee et al (Cancer Immunol, 1994), Chakraborty et al (Proc. Am. Assoc. Cancer, 1994), or Chakraborty et al (Immunotherapy, 1995). Upon review of Applicant's arguments, the rejection is MAINTAINED and applied to **new claims 69-73. The rejection under the reference of Chakraborty et al (Cancer Research, 4/1/1995) has been withdrawn**.

Applicant specifically points out in the Response filed on April 12, 2001 that the Examiner has not considered the Response dated October 8, 1998 and filed as Paper #14. These arguments have been considered by the Examiner and have not been found to be persuasive.

Applicant argues on pg. 5 that the references were not enabling because the methods and materials for making 11D10 antibody was not available nor distributed to the public. This is contrary to the actual discovery of 11D10 by Applicants because 11D10 was derived by immunizing mice with antigens and hybridomas were then screened for an antibody that had specific activity to bind and inhibit cells expressing HMFG and the antigen had originated from Ab2 family of antigens as disclosed in the Chatterjee et al Antigen/Antibody reference.

Applicant further argues on pg. 6 and again at pages 7-11 of the same response that the sequences were never disclosed before the filing of the instant application and is required to make the instant antibody of 11D10. This again is contrary to the teachings of how Applicant derived at the instant invention of 11D10. Applicant did not try to make the instant antibody by direct sequencing but by immunization of mice with an antigen and then screening for the hybridoma that expressed an antibody that bind HMFG. The antigen was known before the filing of the instant application and the method of making the antibody was disclosed to the public before the filing of the instant application as taught by Chatterjee et al in Antigen/Antibody reference thus having the sequence disclosed to the public is irrelevant because the way in which the antibody was produced was not through direct sequencing. Moreover, the sequence was only disclosed after the filing of the instant application and that sequence is part of the hybridoma which intrinsically expresses both DNA, mRNA and protein of the antibody because it is a B cell and the function of B cells is to make monoclonal antibodies specific for an antigen which is defined by its CDR region, natural to the B cell. The mRNA would have been easily obtainable, made into cDNA and sequences derived or the protein would have been easily sequenced directly upon purification from the B cell itself. Thus the claim to the specific antibody is intrinsic to the hybridoma that was disclosed prior to the filing of the instant application. The same argument by the Examiner also holds true for the arguments as presented on pages 12-13 of the response filed October 8, 1998.

In the instant Response dated April 12, 2001 filed as ppaer number 27, Applicant still argues that the references do not anticipate the claims because the references are not enabling because 1) they do not teach and/or enable obtaining 11D10 antibody and do not disclose the amino acid or DNA sequence for the variable regions of 11D10 and 2) they were not made available to the public prior to filing of the instant patent application. The arguments have been considered but found not to be persuasive. The claims of the instant application is drawn specifically to 11D10 antibody and its CDR region. The scope of the claim reads on the already published antibody that is produced by the hybridoma as disclosed by all the references and by the instant

application which intrinsically contain the amino acid sequences and DNA sequences of the antibody and it very clear to one skilled in the art to obtain the DNA and protein and sequence the antibody to derive at the instant invention. Applicant states that the references are not enabling because it does not disclose the methods on how to derive at the 11D10. It was found by the Examiner that complete disclosure as to how to generate the 11D10 antibody was found both in the Chatterjee (Antigen/Antibody, 1994) reference cited supra and evidenced by previous work also by Chatterjee et al (J. of Immunology, Vol. 141:1398-1403, 1988, see materials and methods) and of which was cited as a reference in the Antigen/Antibody reference by Chatterjee et al. Another reference that also disclose the specific methodology on how to derive at 11D10 was also referenced by the Chatterjee et al Antigen/Antibody publication cited as reference #14 which was available to the public before the filing of the instant application. One of ordinary skill in the art could have taken the disclosed methods describe by these references and derive at the 11D10 hybridoma producing the claimed antibody. Therefore, while the specific hybridoma was not available to the public, the method of making said hybridoma was easily available to the public and one of ordinary skill in the art would have been able to make the hybridoma from what was taught by Chatterjee et al (Antigen/Antibody, 1994 or J. Immunology 1988). It is noted that the hybridoma was a derivative of the Ab2 anti-idiotype antibody (Antigen/Antibody, 1994, materials and methods).

Applicant is also reminded that the statutes of 102(b) also states that :

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) **the invention was patented or described in a printed publication in this or a foreign country** or in public use or on sale in this country, **more than one year prior** to the date of application for patent in the United States.

3. All other rejections as cited in the previous office action are hereby withdrawn upon review of Applicant's amendment to the claims.

NEW REJECTION

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 20-27, 31-33, 36-37, 39-40, 42-43, 54-56, 59-65, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (Antigen and Antibody Molecular Engineering, cited Supra) in view of Adair et al (WO

Claims 1-5, 20-27, 31-33, 36-37, 39-40, 42-43, 54-56, 59-65, 67-68 are drawn to a polypeptide having immunological activity of 11D10 comprising the CDR regions of 11D10 or a fusion polypeptide thereof or a humanized antibody thereof.

Chatterjee et al (Antigen and Antibody, 1994) teaches a method of making the 11D10 antibody but differ from the instant application by not disclosing a fusion polypeptide of 11D10 or a humanized antibody of 11D10.

Adair et al disclosed a method of making a humanized antibody (which is also a fusion protein) but differ from the instant application by failing to disclose 11D10 antibody.

Therefore, it would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Chatterjee et al with Adair et al to derive at the instant invention with a reasonable expectation of success. One would have been motivated because it was taught by Chatterjee et al that the 11D10 antibody was an antibody that bound to the HMGF found on breast cancer cells. The scope of the claim impinge upon the epitope binding region of 11D10 comprising the CDR region that have specificity to the HMGF antigen and Chatterjee et al does teach how to make the 11D10 antibody that intrinsically contain the CDR regions specific for HMCF antigen and was successful in using it to find HMGF antigen on breast cells (see pg. 140 of Chatterjee et al Antigen and Antibody reference).

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mau Tran whose telephone number is 703-605-1165. The examiner can normally be reached on Monday-Friday from 8:00 a.m. – 5:30 p.m. with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Mau Tran, Ph.D.
Patent Examiner, Art Unit 1642
April 24, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER